Final report

Explorative study of the influence of the mobileFloww device on the circulation of the blood flow in the ear using Cytocam incident dark field (IDF) video microscopy

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Conflicts of interest

No conflicts of interest are present for the investigators or for the data regarding TVD, PVD and MFI. For the raw data analysis a conflict of interest is present since the data analysis support has been done by an employee of Floww.

Introduction

Scientific studies confirm that electromagnetic radiation (EMR) (such as from mobile phones, computers, GSM or UMTS masts) can have adverse effects on the body. Anecdotal studies reveal that EMR has a direct influence on the clotting of red blood cells in mobile telephone use (e.g. Krylov et al., 2010), which could be reversed by the use of contra-harmful radiation devices (e.g. Huebner, 2010). Floww Health Technology is designed to eliminate the adverse symptoms of radiation and to support and enhance the natural energy of the body by converting harmful radiation into body friendly radiation frequencies (Westerman, 2013). Anecdotal evidence claims that the Floww Health Technology helps to promote and maintain a sense of well-being and vitality in the body, however to date there is a lack of scientific evidence supporting these claims.

Aim of the study

The aim of this pilot study is to assess the influence of the Floww contra-harmful-radiation device on the circulation of blood flow during mobile telephone use.

The theory behind Floww products is that they help neutralise the effects of electromagnetic radiation from devices(Westerman, 2013). Various studies have shown that the Ca2+ balance in cells will change due to the influence of mobile phone radiation and/or its related stress increase (Pall, 2013; Spieker et al.,2002; Weir, 1993; Picano, 2009). These changes in Ca2+ can increase the vascular contraction, thus lowering vessel diameter and increasing blood flow speed. The Ca2+ increase due to stress forms a part of the NO/ONOO cycle, resulting in lowered ability of cells to communicate and/or adapt properly through all available channels (Pall, 2013).

The hypotheses for this study based on the theory behind the Floww products are:

1. The speed of the blood flow with the use of Floww products will be lower than without;
2. The diameter of the blood vessels with the use of Floww products will be bigger than without;
3. The volume of the blood flow through the blood vessels with the use of Floww products will be bigger than without;
4. The Mean Flow Index (MFI) with the use of Floww products will be lower than without;
5. The Perfused Vessel Density (PVD) with the use of Floww products will be lower than without.

The reason that the speed is expected to decrease and the volume to increase, is due to the expected widening of the vessels due to relaxation. The same holds for the MFI and PVD.

Ethics Approval

Approval for this study has been obtained from Teesside University School of Social Sciences Ethics Committee.

Participants

Seven male volunteers from the general public with self reported good health and unknown physical diseases were admitted to this study.

Protocol

After the participant read and signed the informed consent form, he was asked to take place on a chair next to the Cytocam IDF hand held video microscope attached to a computer.   The device consists of a pen-like probe incorporating incident dark field illumination with a set of high resolution lenses projecting images on to a computer controlled high-density image sensor synchronized to an illumination unit. The probe is covered by a sterilisable cap. Cytocam-IDF imaging is based on the incident dark field illumination (IDF), a principle originally introduced by Sherman, Klausner & Cook (1971). It further incorporates a stepping motor for quantitative focusing as well as high resolution optics. This device has recently been validated in the literature for providing microcirculatory images of the human microcirculation (Aykut, 2015). The images were analysed using specialised image processing software (Dobbe, 2008) in line with an international consensus on the microcirculatory parameters, which is needed to describe its function (DeBacker, 2007) . These parameters included the microcirculatory flow index (MFI), total vessel density (TVD) and perfused vessel density (PVD) (De Backer, 2007). Because of the specific focus of the MFI, TVD and PVD, the raw data obtained with the Cytocam were analysed separately as well.

At each time point of measurement (T), the researcher held the hand held video microscope for about one minute at three sites of the back of the ear (placed with the least amount of hair and good visibility of flowing cells) before and after the volunteer had used the mobile phone. Images were collected and the mean values of the microcirculatory parameters of the obtained images of the three sites were calculated. At T0: baseline measurements were taken without use of mobile phone. Next, the participant was asked to hold the mobile phone turned on to the ear for 5 minutes. At T1 once more measurements were made and mean value calculated. Participant was then asked to relax for 5 minutes not using a phone. At T3 measurements were made and mean values calculated. After that, participant held the phone with the Floww device attached to the phone with the phone switched on to the ear for 5 minutes. At T4 measurements were taken and a mean value calculated.

Instrumentation

Use was made of the same mobile telephone with or without a mobileFloww attached to it. The mobile phone was a standard Smartphone. The mobileFloww device consists of a circuit in a small squared metal knob which can be fixed to the back of the mobile phone by means of a removable self-sticking layer. Observations of the blood circulation were accomplished using the Cytocam, a novel third-generation computer controlled imaging sensor based microscope, which incorporates Incident Dark-Field (IDF) (Aykut et al., 2015, Sherman et al., 1971). Microcirculatory blood circulation was imaged using this hand held microscope on the skin surface.

Data analysis

Three microcirculatory parameters were analysed with the image processing- and Cytocam software: TVD, PVD and MFI which describe the functional state of the ear microcirculation at each location (per time point 3 recordings were made at different locations at the back of the ear and these were averaged). TVD is the Total Vessel Density (mm/mm2), PVD is the Perfused Vessel Density ; this is the density of vessels in which there is flow (always equal to or less than TVD) and MFI is a microcirculatory flow index which gives a value for the flow in the vessels. In this study a value of 3 indicates a normal flow and 0 a no flow.

The raw data were combined with Excel for the measurements of all seven participants, both across participants and categories as well as across participants per category. The averages and t-tests were calculated with the built-in excel functions and functions from the data analysis tool-pack. In this research, two-sample t-test assuming unequal variances was calculated for the GSM and Floww groups. From the raw data, the vessel diameter (Diameter), the blood flow speed (Speed), the measured vessel length (Length) and the number of occurrences for each category (Count) were analysed. In addition, the volume of the blood flow was calculated (with the formula $Q = \left(\frac{D}{2}\right)^2 .\pi.V$ where Q is the volume per second)

Results

The results for the MFI, PVD and TVD are detailed in Table 1 below.

MFI	Std Deviation	Confidence Interval
2.385173571	0.322492012	0.238901036
2.689555833	0.25217809	0.186812711
2.373493571	0.270670062	0.200511504
2.088617048	0.640173489	0.474238443
PVD	Std Deviation	Confidence Interval
13.01190071	4.33541132	3.211658636
11.51114833	2.810761005	2.08220263
12.2336469	2.390560314	1.770919322
8.073632048	2.640921099	1.956385779
TVD	Std Deviation	Confidence Interval
13.61047238	4.329557432	3.207322094
11.56935222	2.791084587	2.067626404
13.00449119	2.254816357	1.670360639
9.825137857	2.316745589	1.716237614

The results from the raw data without rescaling for the MFI were also analysed, the overall results are detailed in Tables 2, 3, 4, 5 and 6 below.

Overall Diameter			
	Mean	SD	Conf.Int
BL	12.2054	2.100373	0.898328
GSM	11.63595	1.888604	0.925399
REL	11.59394	1.250552	0.577715
FL	11.98206	1.87199	1.386764

Overall Speed			
	Mean	SD	Conf.Int
BL	2.789321	0.079157	0.033855
GSM	3.118816	0.701387	0.343673
REL	2.720118	0.059709	0.027584
FL	2.865171	0.361798	0.268019

Overall Length			
	Mean	SD	Conf.Int
BL	67.88653	9.406579	4.023186
GSM	66.91502	11.24102	5.508
REL	66.08236	6.833524	3.156869
FL	82.53035	23.36898	17.31166

Overall Volume			
	Mean	SD	Conf.Int
BL	404.6147	82.39219	35.23907
GSM	433.2267	114.2736	55.99303
REL	366.7545	54.50026	25.17737
FL	402.4082	87.28589	64.6611

Overall number of occurrences per category			
	None	Sluggish	Normal
Mean	238.75	1375	1847

The data were also analysed for the categories as they are used for the MFI index from the raw data, these categories are None (slow blood flow speed), Sluggish (slower than normal blood flow speed) and Normal (normal blood flow speed). The results are detailed in Table 7 and 8 below.

Results per category								
Mean Diameter: None					Mean Speed: None			
	Mean	SD	Conf.Int			Mean	SD	Conf.Int
BL	8.496577	2.989393	2.214532		BL	1.86243	0.062063	0.045976
GSM	5.421803	2.269756	1.989492		GSM	1.867788	0.03606	0.031608
REL	7.692479	2.974462	2.380022		REL	1.775975	0.073612	0.058901
FL	10.00919	4.157182	4.073963		FL	1.685929	0.236804	0.232064
Mean Diameter: Sluggish					Mean Speed: Sluggish			
	Mean	SD	Conf.Int			Mean	SD	Conf.Int
BL	12.3491	2.427618	1.798371		BL	2.571063	0.113223	0.083875
GSM	11.30223	1.9704	1.576619		GSM	2.68707	0.124315	0.099471
REL	11.66716	1.509063	1.117909		REL	2.632785	0.090351	0.066932
FL	10.68119	3.141014	2.326853		FL	2.511962	0.131582	0.097475
Mean Diameter: Normal					Mean Speed: Normal			
	Mean	SD	Conf.Int			Mean	SD	Conf.Int
BL	15.77051	1.102006	0.816362		BL	3.934469	0.269144	0.199381
GSM	15.57669	1.355	1.084206		GSM	4.120239	1.08506	0.868213
REL	15.42219	1.055938	0.782235		REL	3.751594	0.214117	0.158617
FL	14.93784	0.637247	0.472071		FL	4.147684	0.713147	0.528297

Results per category								
Mean Length: None					Mean Volume: None			
	Mean	SD	Conf.Int			Mean	SD	Conf.Int
BL	49.13232	9.296237	6.886623		BL	119.2894	61.03312	45.21314
GSM	40.56366	6.497724	5.695401		GSM	52.16715	34.92075	30.60883
REL	46.11178	14.32139	11.45929		REL	99.257	61.14387	48.92439
FL	94.05035	71.96876	70.52809		FL	150.1617	92.43146	90.58116
Mean Length: Sluggish					Mean Volume: Sluggish			
	Mean	SD	Conf.Int			Mean	SD	Conf.Int
BL	71.93759	14.19978	10.51915		BL	325.4499	91.29033	67.62758
GSM	64.16296	12.39756	9.919929		GSM	304.3233	105.2534	84.2187
REL	69.61696	7.362514	5.454126		REL	300.8398	59.21235	43.86432
FL	71.26728	12.25083	9.075372		FL	301.3016	121.6033	90.08331
Mean Length: Normal					Mean Volume: Normal			
	Mean	SD	Conf.Int			Mean	SD	Conf.Int
BL	82.58968	11.58026	8.578619		BL	769.1049	116.7222	86.46739
GSM	84.94014	11.04771	8.839848		GSM	766.4491	121.4026	97.14051
REL	82.51833	9.274021	6.870164		REL	700.1666	96.23602	71.29133
FL	85.69775	17.30977	12.82302		FL	710.4029	103.9923	77.03719

During analysis, it became apparent that there had been a shift in distribution among the number of data points present in each category, as shown in the table below.

	% of occurrences		
	None	Sluggish	Normal
BL	6.05%	43.15%	50.80%
GSM	1.56%	29.03%	69.41%
REL	7.50%	42.98%	49.52%
FL	12.33%	41.13%	46.55%

Statistical analysis

The differences between groups were analysed for TVD, PVD and MFI with a one-tailed two-sample t-test. The results for PVD and MFI were significant.

PVD					
	Mean	Variance	t-crit	t	p
GSM	11.51115	7.900377	1.812461	2.075738	0.032329
FL	8.073632	6.974464			

MFI					
	Mean	Variance	t-crit	t	p
GSM	2.689556	0.063594	1.859548	2.111191	0.033874
FL	2.088617	0.409822			

The raw data were analysed the same way. The results for Speed and Length were not significant, as were the results for Diameter and Volume for groups Sluggish and Normal. The results for Diameter and Volume were significant for the category None.

Vessel diameter: category None					
	Mean	Variance	t-crit	t	p
GSM	5.421803	6.869057	1.859548	-2.01681	0.039223
FL	10.00919	20.73859			

Blood flow volume, category: None					
	Mean	Variance	t-crit	t	p
GSM	52.16715	1625.945	1.894579	-2.13072	0.035298
FL	150.1617	10252.29			

The differences in the occurrence of data point in the three categories were significant for the category Normal.

Number of occurrences, category: Normal					
	Mean	Variance	t-crit	t	p
GSM	166.9444	5439.074	1.859548	2.318997	0.024498
FL	87.45238	1879.59			

Conclusion

The study set out to investigate both the measurement protocol with the Cytocam and the differences between the use of a mobile phone with and without Floww technology. These goals have been achieved. The measurement protocol as such is feasible and gives movies from which functional parameters can be determined, and a difference with and without Floww technology has been shown to be present with the Cytocam.

The results show that not all hypotheses can be accepted. Hypothesis 1 is rejected. Hypothesis 2 and 3 are rejected for groups Sluggish and Normal, but are accepted for the group None. Hypothesis 4 and 5 are accepted. This means that:

- the vessel diameter is significantly bigger with Floww technology for category None;
- the volume of blood flow is significantly bigger with Floww technology for category None;
- the MFI is significantly lower with Floww technology;
- the PVD is significantly lower with Floww technology.

The interpretation of these results can be tentatively described as a larger relaxation of the vessel wall with the use of Floww technology than without, thereby causing the blood flow to slow because of the exponential influence the vessel diameter has on the blood flow while still putting through a larger volume of blood. Because of the relaxation of the vessel wall, the blood flow is expected to drop in speed and will therefore cause a lower MFI flow index as well as a lower Perfused Vessel Density since this index is dependent on the categorisation of the blood flow speed into the three categories (None, Sluggish, Normal). The lower scores on MFI, PVD and blood flow speed therefore do not mean a worsening by definition. That these variables only show part of the overall picture can be seen through the increase of blood flow volume and the calculation of TVD, as vessel density (TVD), is calculated with the camera field of view area and the vessel length. The vessel diameter is not taken into account directly this way, although vessel diameter is related to stress factors through changes in the Ca2+ balance in smooth muscle cells in the vessel wall.

The reason why Diameter and Volume only achieved significance in the category None is potentially twofold. First, the results from the Floww intervention show a shift in the distribution of the data points across the categories, thereby favoring the category None for showing an effect. Especially since the number of occurrences in the category None is much smaller than the number of occurrences in categories Sluggish and Normal. Second, the blood flow speed can be assumed to have an individual optimum. The body will regulate much stronger in non-optimal conditions, and blood flow is assumed to be no exception to that. Any effects would therefore be much more likely to show up in situations that deviate from the optimum, being in this case primarily the category None and possibly secondary the category Sluggish. These interesting findings might be due to the length of time per intervention, but this need to be investigated further.

Follow-up research is needed with blinding to avoid any placebo and/or other bias and a larger test group, and may provide a good starting point to further detail the working mechanisms of Floww technology if it is expanded with, for instance, white blood cells because of their relation with inflammations.

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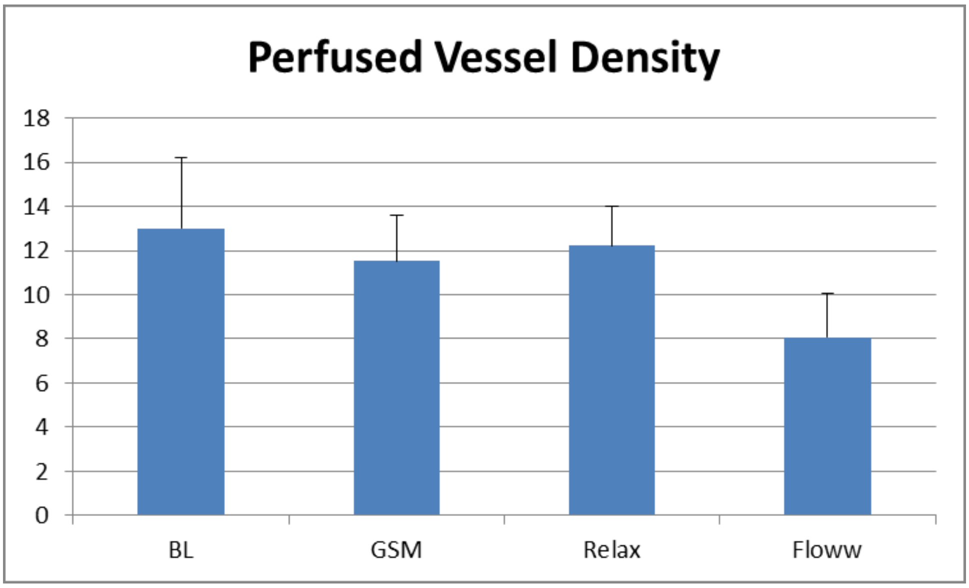
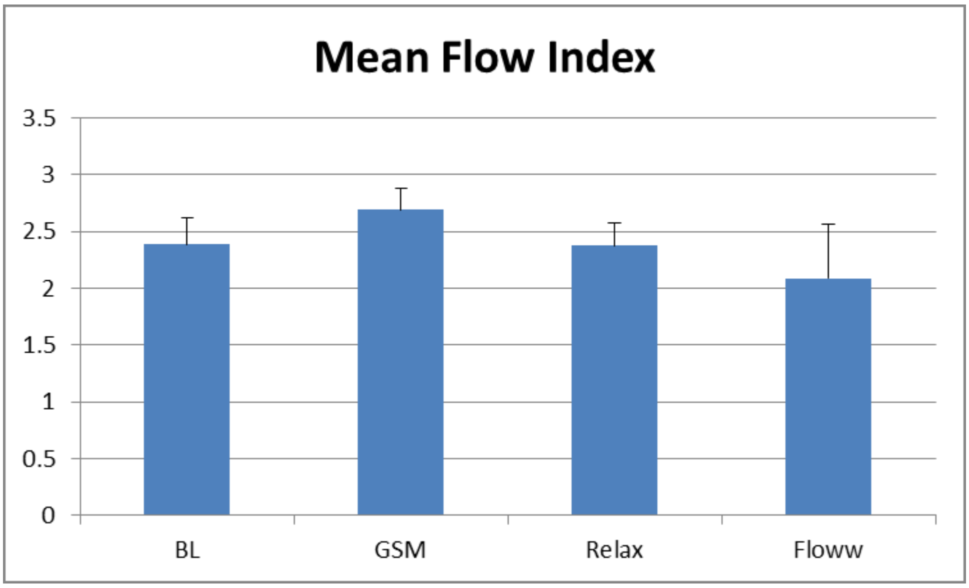
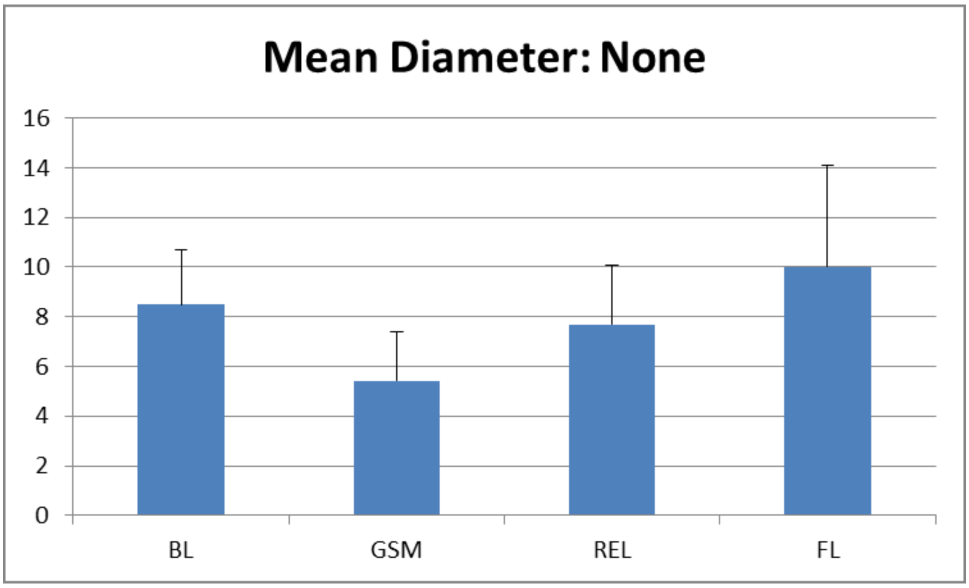
Graphs



Perfused Vessel Density
18
16
14
12
10
8
6
4
2
0
BL
GSM
Relax
Floww



Mean Flow Index
3.5
3
2.5
2
1.5
1
0.5
0
BL
GSM
Relax
Floww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6
4
2
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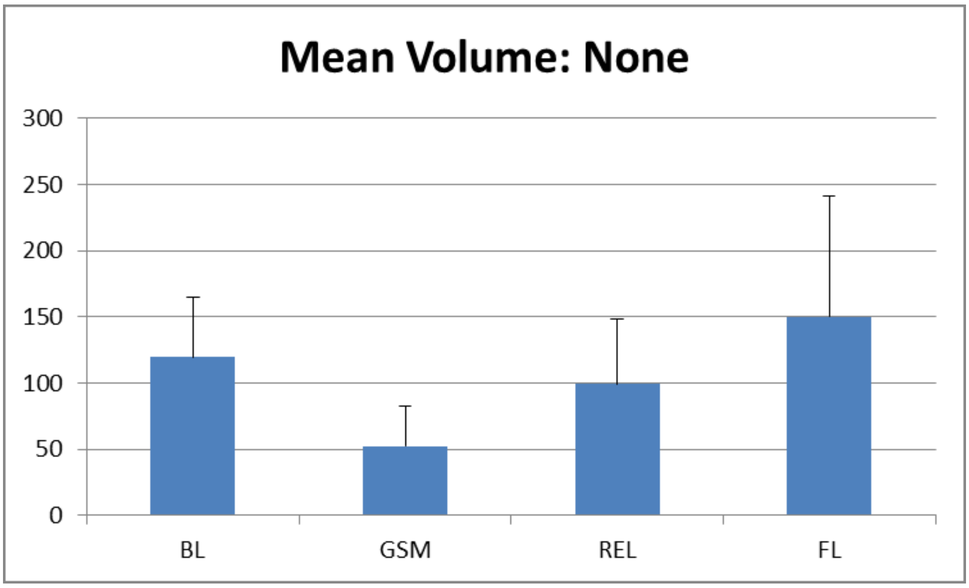
BL
GSM
REL
FL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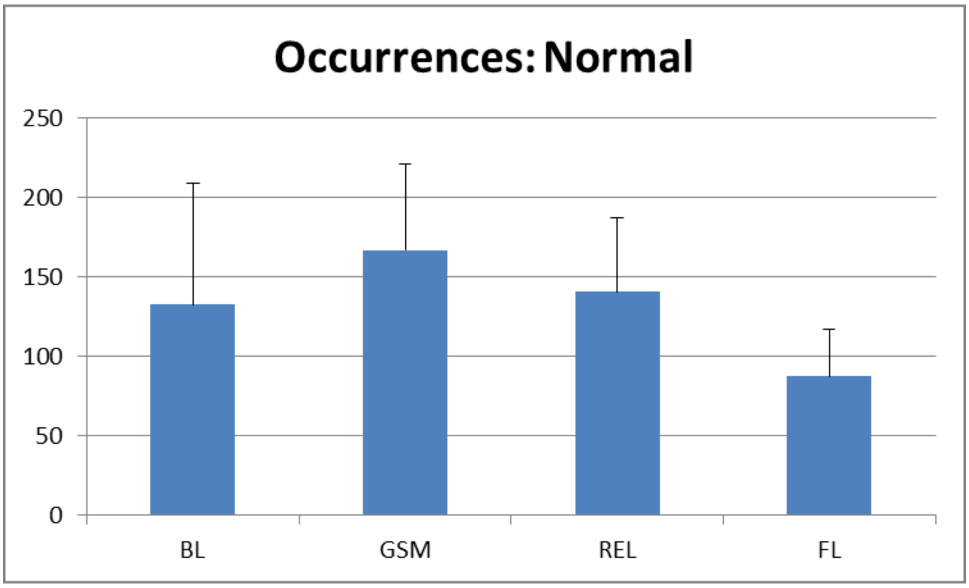
50
0
BL
GSM
REL
FL


Occurrences: Normal
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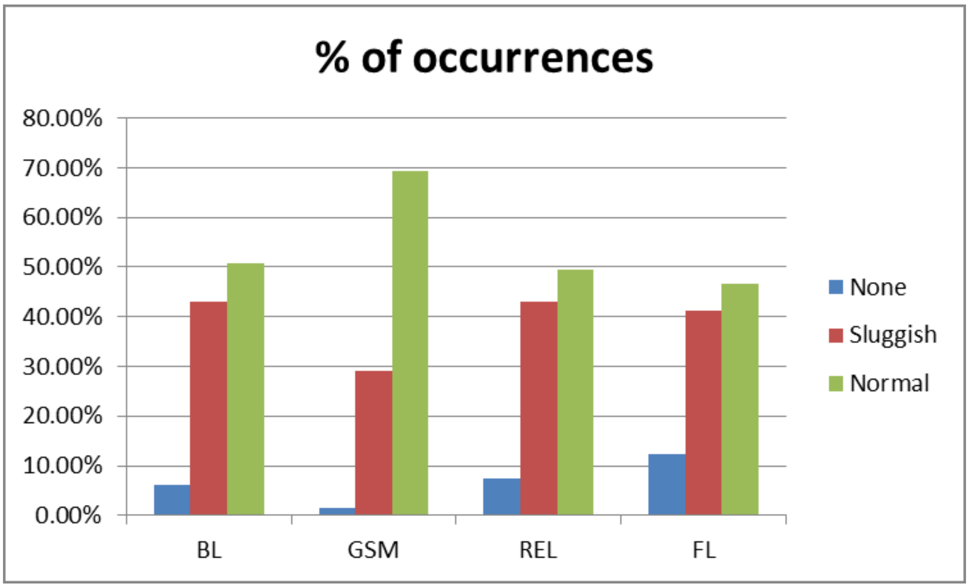
200
150
100
50
0
BL
GSM
REL
FL


% of occurrences
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
BL
GSM
REL
FL
None
Sluggish
Normal